

REMARKS

Claims 41-75 and 84-97 were previously cancelled. Claims 1, 14 and 98 have been amended. Claims 98-109 were previously added. Claims 1-40, 76-83 and 98-109 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejections under 35 U.S.C. § 112

Claims 98-109 are rejected under 35 U.S.C. § 112 as being allegedly non-enabled. The Examiner alleges that claims 98-109 are non-enabling because "the specification, while being enabling for encapsulation of pancreatic cells, does not reasonably provide enablement for all claimed cells". Further, the Examiner states that the specification in paragraph 48, describes densities for pancreatic cells only. Applicants respectfully traverse the rejection as follows.

The Examiner asserts that Applicants only describe encapsulation of "pancreatic cells" and not any other type of cell. Applicants submit that the specification provides support for encapsulating other than pancreatic cells (Examples 1-11 of the specification). For example, Example 12 and corresponding FIGs. 28- 30, describe viability post-encapsulation of "mouse insulinoma, cell line [FIG.28; paragraph 312]", "a monkey kidney cell line [FIG. 29A; paragraph 313]; and "cell aggregates produced from primary liver cells (hepatocytes) from both human and mouse origin [FIG.30; paragraph 314]". All cells were "successfully" coated and viable post-encapsulation based on fluorescent light with FDA/EB staining. Additionally, Examples 15-20 of the specification, describe encapsulation of human or animal fibroblasts, vascular cells, or various non-tumorigenic cell lines, and genetically engineered cell lines for encapsulation (paragraphs 328-333 of the specification). Further, Examples 1-11 of the specification, clearly describe the encapsulation of pancreatic islets that the skilled artisan based on these descriptions can apply these to other cell types without undue experimentation. Examples 12-15 of the specification show that the using substantially the same methods as that described for encapsulation of pancreatic cells, Applicants were able to encapsulate lung (Figure 29) and primary liver cells (Figure 30), and further demonstrating that these cell types remained viable at

least up to 2 weeks post-encapsulation. Therefore, it is clear that cells other than pancreatic cells are encompassed and anticipated by the claimed invention; and that Applicants have sufficiently described and enabled the skilled artisan to do such.

The Examiner also states that the specification in paragraph 48, describes densities for pancreatic cells only. Applicants respectfully submit that the Examiner appears to be contradictory in this and the obviousness rejection below. Because at the same time the Examiner alleges that Applicants only describe densities for pancreatic cells and not other cell types, in the obviousness rejection below, the Examiner alleges that cell densities per se are within the skill of one in the art. Thus, if cell densities are allegedly “within the skill of one in the art” then Applicants written description of pancreatic cell densities is more than sufficient to provide teachings for other cell types.

However, independent of the obviousness rejection, from Examples 12-14 and Tables 3-6 of the specification, it is clear that Applicants clearly describe how to determine the “curative dose” of cells which should and can be encapsulated. Tables 3-6 lay out the parameters and provide guidance to the skilled artisan. Thus, determining cell densities of other cell types requires some experimentation but not undue experimentation.

Therefore, Applicants respectfully request that the rejections of claims 98-102 based on lack of enablement be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 1-16, 76-83 and 98-109 are rejected under 35 U.S.C. §103(a) as being obviousness over WO 00/53159 (WO'159). Applicants respectfully traverse this rejection as follows.

The Examiner alleges that the claims are obvious over WO'159 because WO'159 describes the identical encapsulation coating except for the cell densities, which the Examiner alleges is within the skill of one in the art.

Claims 1, 14 and 98 have been amended to recite that the composition comprises a “covalently polymerizable high density ethylenically unsaturated PEG (claims 1 and 14)” or a “covalently linked polyethylene glycol (PEG) coating (claim 98)”.

Applicants submit that the claimed invention is distinguished over WO'159 because the claimed invention is directed to only a “covalently polymerizable high density ethylenically unsaturated PEG (claims 1 and 14)” or to a “covalently linked polyethylene glycol (PEG) coating (claim 98)”. Also, see Example 3, paragraph 241. In contrast, WO'159 describes alginate/PEG complexes which are ionically and covalently linked. WO'159 describes that the alginate beads had to be modified by ionically incorporating acrylate groups onto the alginate using conventional coaxial pneumatic nozzle technique (page 34, line 30; and page 35, line 5 of WO'159). In order to get the modified alginate beads, there is a soaking step which takes at least between about 1-5 minutes (Table on page 35 of WO'159). The claimed invention by providing a one step cross-linking method of encapsulation (photoinitiator and argon laser; Example 3, paragraph 241 of the specification) is simpler, can be performed in one step, and thus improved over that of WO'159 which requires a two (2) step process of ionically (alginate; page 35, line 4 of WO'159) and covalently (PEG) linking the encapsulation device/composition. Also, a two step process of encapsulating cells is likely to jeopardize the viability and integrity of the cells.

In view of Applicants' amendments and arguments, withdrawal of the above grounds of rejection is respectfully requested.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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